UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LEAH ROYCE HINES,

Plaintiff,

v. Civil Action No. 2:04-0690

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is defendants' motion to exclude the expert testimony of Drs. Suzanne Parisian, Cheryl Blume, and Donald Austin (Doc. No. 274), filed May 27, 2011.[1]

In her response, plaintiff clarifies that she will not call Dr. Austin to testify at trial concerning the reasonableness of defendants' conduct. (Pl.'s Opp. at 4). The court accordingly ORDERS that defendants' request to exclude his testimony on the grounds stated in the motion be, and it hereby

[1] At a pretrial conference on June 17, 2011, the court conferred with counsel regarding the necessity of an evidentiary hearing on the various Daubert motions currently pending before the court. (See Doc. No. 343). The parties made clear that such a hearing was not necessary. Defendants have, however, requested oral argument on the motions. Inasmuch as the parties' briefs and supporting exhibits adequately present the issues ripe for adjudication, the court finds that oral argument would not aid the decisional process and accordingly denies defendants' request for oral argument as to the present motion.

is, denied as moot.

I. Background

This is a pharmaceutical products liability action in which plaintiff Leah Royce Hines alleges that she developed breast cancer as a result of ingesting hormone replacement therapy ("HRT") drugs manufactured by defendants. HRT here consists of two medications, estrogen and progestin ("E+P"), that are commonly prescribed in combination to treat menopausal symptoms.

This action concerns three HRT drugs: Premarin, Prempro, and Provera. Defendant Wyeth, LLC ("Wyeth") manufactured Premarin, an estrogen drug, and Prempro, a combination estrogen and progestin drug. Defendant Pharmacia & Upjohn Company ("Upjohn") manufactured and distributed Provera, a progestin drug. The generic name for Provera is medroxyprogesterone acetate ("MPA").

Plaintiff's physician prescribed HRT drugs to treat her menopausal symptoms from approximately 1994 to April 1999. She was diagnosed with breast cancer in July 1999, and thereafter instituted this action on July 7, 2004, invoking the court's

diversity jurisdiction.[2] Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of implied warranty.

Defendants seek to exclude the testimony of two of plaintiff's expert witnesses: Drs. Parisian and Blume.

II. Governing Standard

The admission of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Under Rule 702 and Daubert, expert testimony must satisfy a two-prong test: (1) the testimony must concern "scientific, technical, or other specialized knowledge"; and (2) it must "aid the jury or other trier of fact to understand or resolve a fact at issue." Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999) (citing Daubert, 509 U.S. at 592); Fed. R. Evid. 702. "The first prong of this inquiry necessitates an examination of whether the reasoning or methodology underlying the expert's proffered opinion is reliable -- that is, whether it

[2] The case was transferred to multidistrict litigation in the United States District Court for the Eastern District of Arkansas on October 26, 2004. Over five years later, on April 13, 2010, it was remanded to this court for the completion of discovery, pretrial activity, and trial.

is supported by adequate validation to render it trustworthy." Id. "The second prong of the inquiry requires an analysis of whether the opinion is relevant to the facts at issue." Id. Thus, an expert's testimony is admissible under Rule 702 if it "rests on a reliable foundation and is relevant." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

As to the reliability prong, the Court in Daubert announced a non-exhaustive list of factors to guide the trial judge's inquiry, including "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing Daubert, 509 U.S. at 592-94).

As to the relevancy prong, "the expert's proffered scientific testimony must be sufficiently tied to the facts of the case that it will be of assistance to the factfinder in resolving a disputed fact." Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., 189 F. Supp. 2d 482, 495 (S.D. W. Va. 2002). "That is, there must be a 'valid scientific connection to the

pertinent inquiry' before the testimony is admissible." Id. (quoting Daubert, 509 U.S. at 591-92).

Our court of appeals has summarized the overarching duties of a trial court in resolving Daubert motions as follows:

> A district court considering the admissibility of expert testimony exercises a gate keeping function to assess whether the proffered evidence is sufficiently reliable and relevant . . . The inquiry to be undertaken by the district court is "a flexible one" focusing on the "principles and methodology" employed by the expert, not on the conclusions reached. Daubert, 509 U.S. at 594-95 . . . In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful . . . The court, however, should be conscious of two guiding, and sometimes competing, principles. On the one hand, the court should be mindful that Rule 702 was intended to liberalize the introduction of relevant expert evidence. . . . [T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct . . . As with all other admissible evidence, expert testimony is subject to being tested by "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596 . . . On the other hand, the court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to "be both powerful and quite misleading." Id. at 595 . . . [G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.

Westberry, 178 F.3d at 261 (some citations and footnotes omitted). Ultimately, "[t]he proponent of the [expert] testimony must establish its admissibility by a preponderance of proof."

Cooper, 259 F.3d at 199.

III. Motion to Exclude

A. Background

Plaintiff seeks to admit the testimony of Drs. Parisian and Blume to demonstrate that defendants conducted insufficient testing prior to and after releasing their HRT drugs and provided inadequate warnings regarding the link between their drugs and breast cancer. Notably, in briefing the admissibility of the proposed expert testimony, the parties devote much of their discussion to Dr. Parisian and reference Dr. Blume only in passing. Indeed, the parties did not include with their briefing Dr. Blume's expert report or her deposition testimony in this matter, nor do they cite these documents in arguing for or against the admissibility of her testimony. Accordingly, in assessing this Daubert motion, the court will assume, as do the parties, that the testimony of Dr. Blume would be analogous to that of Dr. Parisian, whose expert report has been included for the court's review.

Dr. Parisian begins her lengthy expert report, which spans nearly three hundred pages, with a discussion of her qualifications and extensive background as a former examiner with

the Food and Drug Administration ("FDA"). Part II of her report, entitled "Executive Summary," then lays out the roles of both the FDA and pharmaceutical drug manufacturers in monitoring the safety and effectiveness of pharmaceutical drugs. Dr. Parisian concludes Part II by summarizing how a responsible manufacturer introduces and promotes pharmaceutical drugs:

> A responsible pharmaceutical manufacturer will promote its drug's use by fair and balanced marketing and not disregard the requirements of the [Federal Food, Drug, and Cosmetic Act ("FD&C Act")]. A responsible drug sponsor does not promote its drug for new off-label/unapproved use, particularly when there is data that suggests that use is not safe or effective. A responsible manufacturer does not provide physicians and patients with false and misleading labeling through use of public relations agencies, 3rd parties, [or] reimbursed advocates. A responsible manufacturer upon becoming aware that its product is being used in combination with another drug would update its label, warnings and instructions to ensure compliance with [the FD&C Act] and to protect patients.

(Pl.'s Resp., Ex 23a, Expert Report of Suzanne Parisian, M.D. ("Parisian Rep."), at 12). Dr. Parisian does not reference any particular regulation or requirement of the FDA in setting forth this standard. She concludes Part II with a general citation to Appendix 4, discussed below.

Part III of Dr. Parisian's expert report, entitled "Opinions," purports to apply the standard set forth above to the facts of this case, resulting in nine separate opinions

concerning the adequacy of defendants' testing procedures and warnings. Specifically, Dr. Parisian opines as follows:

1. Defendants breached their duty as responsible pharmaceutical manufacturers under the FD&C Act when they marketed their HRT drugs "without having done appropriate testing, monitoring, or obtaining FDA's approval";

2. Defendants should have "voluntarily conducted case-control studies and other observational studies" when the scientific community began to discover a link between breast cancer and HRT;

3. Nothing in the FD&C Act would have prohibited defendants from "voluntarily conducting post-approval safety studies" or "voluntarily improving its own product label";

4. Defendants "failed to investigate and market alternative drugs [they] knew would be safer for women" and delayed completion of scientific research;

5. Defendants continued to market their HRT drugs despite being aware of safer alternatives;

6. Defendants failed to behave as responsible drug manufacturers when they allocated resources and funding to public relations campaigns rather than "monitoring and investigating safety signals" and conducting clinical trials;

7. Defendants "falsely skewed the apparent medical risks versus benefits paradigm" for their HRT drugs;

8. Defendants failed to behave as responsible pharmaceutical managers when they "used false, misleading, and unsupported claims," including unsubstantiated health benefits; and

9. Defendants disregarded the requirements of the FD&C and the warnings of the Food and Drug

> Administration ("FDA") by over-promoting the effectiveness of their drugs.

(Id. at 12-30). Dr. Parisian includes no other discussion with Opinions 2, 3, 5, 6, 8, and 9, which are instead followed only by a list of citations, apparently to documents and/or studies that Dr. Parisian relied upon in reaching each opinion. Opinions 1, 4, and 7 include text in addition to the opinions themselves. For example, Opinion 1 -- that defendants breached their duties as responsible pharmaceutical manufacturers by marketing their HRT drugs without first conducting appropriate testing or obtaining FDA approval -- is followed by three paragraphs of text outlining the introduction of Premarin in 1942, Provera in 1962, and defendants' marketing tactics with respect to each. (Id. at 12-13).

Attached to Dr. Parisian's expert report are two appendices, Appendix 3 and Appendix 4. Appendix 3, entitled "Food and Drug Administration ("FDA") & Human Prescription Drugs," is a twenty-two page summary of the FDA's practices with respect to new drug applications. Dr. Parisian also includes in Appendix 3 a review of several regulations promulgated by the FDA. Dr. Parisian specifically references defendants only once in Appendix 3. (Id., App. 3, at 1-2 (noting that defendants' HRT drugs were available before the relevant regulations were enacted

and thus were not considered new drugs)).

Appendix 4, meanwhile, is a 218-page discussion entitled "Underlying Facts and Data in Support of Opinions." (Id., App. 4, at 1). Appendix 4 is essentially a detailed recitation of the history of Premarin, Prempro, and Provera, focused largely on defendants' efforts to introduce the HRT drugs into the market and to promote those drugs for long-term use. Although the recitation is primarily factual in nature, Dr. Parisian occasionally introduces her own opinions concerning defendants' conduct. For example, to demonstrate that defendants knew or should have known of the risks accompanying their HRT drugs, Dr. Parisian summarizes a 1976 internal document of defendant Wyeth, wherein Wyeth scientists note that HRT drugs are at least capable of accelerating growth of previously established tumors. She follows this discussion with her opinion that the "document should have triggered a responsible manufacturer to begin to perform additional investigation as to the role of hormones for risk of breast cancer before recommending prolonged unopposed and combination hormone therapy." (Id., App. 4, at 173). All told, Dr. Parisian surveys hundreds of defendants' internal documents in Appendix 4, including letters exchanged between defendants and the FDA, memoranda circulated among

defendants' employees, and notes taken during various meetings. She concludes Appendix 4 with a summary of the relevant research available concerning the link between breast cancer and HRT drugs.

Plaintiff contends that the proposed expert testimony of Drs. Parisian and Blume would aid the jury in understanding defendants' "failure to warn in a regulated and technical industry" and would "provide critical evidence on the defective design of the drug[s] and the availability of safer alternatives." (Pl.'s Opp. at 1-2). Defendants, by contrast, maintain that the anticipated expert testimony is unreliable and should be excluded in its entirety. Specifically, defendants emphasize that Dr. Parisian is unable to identify an industry standard of care to show what a reasonable pharmaceutical company would have done when testing and marketing HRT drugs. Absent an objective, verifiable standard of care, Dr. Parisian's testimony, according to defendants, amounts to nothing more than her own personal views. (Defs.' Mem. Supp. Mot. to Exclude at 3).

B. Analysis

Following an extensive review of Dr. Parisian's expert report and the parties' thorough briefing on this matter, the

court is constrained to conclude that plaintiff has failed to satisfy her burden of demonstrating admissibility. Put simply, the proposed expert testimony is riddled with conclusory statements lacking either analysis or explanation; improperly touches on issues well beyond the experts' qualifications; and, at times, merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness. Because of these deficiencies, the court finds that the testimony is neither relevant nor reliable under Daubert and Rule 702.

1. Conclusory Statements Unsupported by Analysis

Perhaps most problematic, the court cannot find that the proposed expert testimony is anything more than a personal belief or opinion. Dr. Parisian goes to great lengths to criticize defendants' conduct in developing and marketing their HRT drugs, concluding on numerous occasions that defendants failed to act as reasonable pharmaceutical manufacturers. Yet nowhere in her expert report does she explain the basis for these conclusions. See Fed. R. Civ. P. 26(a)(2)(B) (providing that expert report must include, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them" (emphasis added)). Although Dr. Parisian

appears more than qualified to testify as an expert on the rules and regulations of the FDA, she fails to apply this expertise to the facts in this matter. For instance, Dr. Parisian concludes in Opinion 1 of her expert report that defendants breached their duties as responsible pharmaceutical manufacturers when they marketed their drugs without first testing them or obtaining FDA approval. Dr. Parisian follows that opinion, however, with no explanation or analysis. Indeed, she fails to cite a single rule or regulation that would require defendants to act as she suggests they should have, nor does she in any other way provide the grounds for her conclusion that a responsible manufacturer would have behaved differently. Each of the remaining eight opinions is similarly devoid of any explanation or analysis. Inasmuch as Dr. Parisian has provided no grounds for her testimony, the court concludes that it is mere personal opinion and thus inadmissible. See Fed. R. Evid. 702 (providing that expert testimony is admissible if "based upon sufficient facts or data"); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) ("[N]othing in Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion offered.").

Notably, other courts in the HRT litigation have excluded the testimony of Drs. Parisian and Blume for the very reason articulated above. For example, in the multidistrict litigation proceedings, the Eastern District of Arkansas granted a post-trial motion to strike the testimony of Dr. Parisian, finding that her testimony at trial "was hardly expert in nature" inasmuch as she had failed to apply any relevant standard of review to her opinion concerning defendants' conduct. Scroggin v. Wyeth (In re Prempro Prods. Liab. Litig.), 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). Prior to trial, the MDL court had allowed Dr. Parisian to testify to her opinions on the reasonableness of a pharmaceutical company's actions based on her understanding of the regulations referenced in her expert report. Id. at 879. During the liability and punitive damages stages of trial, however, Dr. Parisian gave only a "cursory review of FDA regulations" and merely read select portions of documents in evidence without providing further comment. Id. at 887. Significantly, the MDL court found that Dr. Parisian had offered little analysis for her opinions:

> During the punitive damages stage of trial, Dr. Parisian's testimony tracked Plaintiff's legal arguments, and there was very little significant analysis. On numerous occasions, Dr. Parisian declared "this isn't fair and balanced," but she provided no explanation. Dr. Parisian, no doubt has special

> knowledge and skill regarding FDA operations and regulations, but she did not apply this knowledge and skill to her testimony.

Id. Accordingly, the MDL court excluded her testimony, id., a ruling later affirmed by the Eighth Circuit on appeal, see Scroggin v. Wyeth (In re Prempro Prods. Liab. Litig.), 586 F.3d 547, 571 (8th Cir. 2009) (noting that Dr. Parisian's testimony was "largely devoid of regulatory analysis").

The MDL court reached a similar result in a separate bellwether trial in 2010. See Ingram v. Wyeth, Inc. (In re Prempro Prods. Liab. Litig.), MDL Docket No. 4:03-cv-01507, 2010 WL 5663003 (E.D. Ark. Sept. 16, 2010). In that instance, the MDL court assessed whether Drs. Parisian and Blume could testify "about the reasonable standard of care that Defendants should have followed in the continued testing of HRT after it was placed on the market." Id. at *2. Following a Daubert hearing, the MDL court found that the proposed experts could not identify an established, objective industry standard by which to judge the defendants' conduct. Id. Rather, according to the court, the experts "would only be able to subjectively testify about what companies could do by way of testing rather than what [they] were required to do." Id. (emphasis omitted). Accordingly, the court concluded that the testimony was "too subjective and not expert

in nature" and precluded the experts from testifying at trial. Id. at *3.

The court finds that Dr. Parisians' expert report is similarly lacking in analysis here, rendering the proposed expert testimony unreliable and inadmissible.

2. Testimony Concerning State of Mind and Motive

Also troubling is the fact that Dr. Parisian fails to confine her proposed testimony to her area of expertise, the FDA regulatory scheme. Instead, Dr. Parisian states conclusory opinions regarding defendants' state of mind and knowledge based on her own reading of their internal documents. For example, in addition to her opinion that defendants "falsely skewed the apparent medical risks versus benefits paradigm" associated with their HRT drugs, Dr. Parisian alleges that defendants "develop[ed] working alignments with third party associations that were designed to influence the medical community's beliefs that estrogen/MPA had a low association with breast cancer and the association with uterine cancer had been virtually eliminated." (Parisian Rep. at 27). Inasmuch as Dr. Parisian has no knowledge concerning defendants' state of mind or intent, the court would be hard pressed to allow her to opine at trial on

defendants' motives in forming alliances with third parties. See In re Trasylol Prods. Liab. Litig., 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding Dr. Parisian's testimony in part because her expert report "makes conclusory opinions regarding Bayer's and the FDA's state of mind and knowledge"); see also Lopez v. I-Flow, Inc., Nos. CV 08-1063, 2011 WL 1897548, at *11 (D. Ariz. Jan. 26, 2011) (concluding that Dr. Parisian's proposed testimony lacked reliability because, inter alia, she "opines as to the knowledge, state of mind, intent or motivations of I-Flow, other Defendants[,] or the FDA itself"). Inasmuch as the proposed expert testimony goes beyond the experts' qualifications, the court finds it inadmissible.

3. Unhelpful to the Jury

Finally, the court notes that much of the anticipated expert testimony would actually invade the province of the jury rather than assist it in resolving material issues of fact. As explained, many of Dr. Parisian's opinions are based on her own reading of defendants' internal documents. Even assuming, as Dr. Parisian suggests, that these documents demonstrate defendants' knowledge of the risks associated with their HRT drugs, the jury is more than capable of reading and summarizing the documents on its own. See Scroggin, 554 F. Supp. 2d at 887 ("Having an expert witness simply summarize a document (which is just as easily

summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony. Because Dr. Parisian's testimony -- or reading -- invaded areas that required no expert assistance, it was inappropriate 'expert' testimony."). The court finds that the proposed expert testimony would provide little assistance to the jury and is thus irrelevant under Daubert.

IV. Conclusion

For the foregoing reasons, the court ORDERS that defendants' motion to exclude the testimony of Drs. Parisian and Blume be, and it hereby is, granted.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record.

DATED: July 8, 2011

John T. Copenhaver, Jr.
United States District Judge